

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF PUERTO RICO

3 MARIA DE LOS A. ROSA,
4 et al.,

5 Plaintiffs,

6 v.
7 CIVIL NO. 03-2399 (RLA)

8 MEDTRONIC MINIMED, INC.,
9 et al.,

10 Defendants.

11 **ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

12 Defendant, Medtronic Minimed, Inc. ("MiniMed"), has moved the
13 Court to enter summary judgment on its behalf and to dismiss the
14 claims asserted against it in these proceedings.

15 In support of its initial summary judgment request, MiniMed
16 alleges: (1) that Angel's DKA episode was due exclusively to his
17 failure to properly monitor his blood glucose levels and not to the
18 connection of the insulin pump and (2) that MiniMed had no duty to
19 warn plaintiff regarding the risk of DKA and even if it did,
20 defendant discharged any such duty to warn. Subsequently, defendant
21 further alleged that it was not liable for Dr. Pijem's acts or
22 omissions because she was an independent contractor.

23 The Court having reviewed the memoranda filed by the parties as
24 well as the evidence submitted in support thereof finds that issues
25 of material fact preclude summary judgment at this stage of the
26 proceedings.

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3 **PROCEDURAL BACKGROUND**

4 This action was instituted by the parents of Angel J. Diaz-Rosa
5 ("Angel") on their own behalf and on behalf of their then minor son¹
6 for alleged damages resulting from Angel's three-day hospitalization
7 for Diabetic Ketoacidosis ("DKA") in 2001. According to plaintiffs,
8 the DKA and subsequent hospitalization were purportedly due to an
9 insulin pump used by Angel which was manufactured by MiniMed and
10 installed by Dr. Gladys Gonzalez de Pijem ("Dr. Pijem"). The
11 complaint, labeled as one for "medical malpractice", was based on our
12 diversity jurisdiction and named MiniMed as well as Dr. Pijem as
13 defendants. Subsequently, plaintiffs voluntarily dismissed the claims
14 asserted against Dr. Pijem in order to preserve the required
15 diversity of citizenship between the parties.² Accordingly, only the
16 causes of action asserted against Minimed remain pending.

17 **SUMMARY JUDGMENT STANDARD**

18 Rule 56(c) Fed. R. Civ. P., which sets forth the standard for
19 ruling on summary judgment motions, in pertinent part provides that
20 they shall be granted "if the pleadings, depositions, answers to
21 interrogatories, and admissions on file, together with the
22 affidavits, if any, show that there is no genuine issue as to any
23 material fact and that the moving party is entitled to a judgment as

24 ¹ Angel became of legal age in April 2005. See Motion Requesting
25 Permission to Amend Complaint (docket No. 34) ¶ 8.

26 ² See Partial Judgment issued on August 13, 2004 (docket No.
17).

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3 a matter of law." Sands v. Ridefilm Corp., 212 F.3d 657, 660-61 (1st
4 Cir. 2000); Barreto-Rivera v. Medina-Vargas, 168 F.3d 42, 45 (1st Cir.
5 1999). The party seeking summary judgment must first demonstrate the
6 absence of a genuine issue of material fact in the record.
7 DeNovellis v. Shalala, 124 F.3d 298, 306 (1st Cir. 1997). A genuine
8 issue exists if there is sufficient evidence supporting the claimed
9 factual disputes to require a trial. Morris v. Gov't Dev. Bank of
10 Puerto Rico, 27 F.3d 746, 748 (1st Cir. 1994); LeBlanc v. Great Am.
11 Ins. Co., 6 F.3d 836, 841 (1st Cir. 1993), cert. denied, 511 U.S.
12 1018, 114 S.Ct. 1398, 128 L.Ed.2d 72 (1994). A fact is material if
13 it might affect the outcome of a lawsuit under the governing law.
14 Morrissey v. Boston Five Cents Sav. Bank, 54 F.3d 27, 31 (1st Cir.
15 1995).

16 "In ruling on a motion for summary judgment, the court must view
17 'the facts in the light most favorable to the non-moving party,
18 drawing all reasonable inferences in that party's favor.'" Poulis-
19 Minott v. Smith, 388 F.3d 354, 361 (1st Cir. 2004) (citing Barbour v.
20 Dynamics Research Corp., 63 F.3d 32, 36 (1st Cir. 1995)).

21 Credibility issues fall outside the scope of summary judgment.
22 "'Credibility determinations, the weighing of the evidence, and the
23 drawing of legitimate inferences from the facts are jury functions,
24 not those of a judge.'" Reeves v. Sanderson Plumbing Prods., Inc.,
25 530 U.S. 133, 150, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000) (citing
26 Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505,

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3 91 L.Ed.2d 202 (1986)). See also, Dominguez-Cruz v. Suttle Caribe,
4 Inc., 202 F.3d 424, 432 (1st Cir. 2000) ("court should not engage in
5 credibility assessments."); Simas v. First Citizens' Fed. Credit
6 Union, 170 F.3d 37, 49 (1st Cir. 1999) ("credibility determinations
7 are for the factfinder at trial, not for the court at summary
8 judgment."); Perez-Trujillo v. Volvo Car Corp., 137 F.3d 50, 54 (1st
9 Cir. 1998) (credibility issues not proper on summary judgment);
10 Molina Quintero v. Caribe G.E. Power Breakers, Inc., 234 F.Supp.2d
11 108, 113 (D.P.R. 2002). "There is no room for credibility
12 determinations, no room for the measured weighing of conflicting
13 evidence such as the trial process entails, and no room for the judge
14 to superimpose his own ideas of probability and likelihood. In fact,
15 only if the record, viewed in this manner and without regard to
16 credibility determinations, reveals no genuine issue as to any
17 material fact may the court enter summary judgment." Cruz-Baez v.
18 Negrón-Irizarry, 360 F.Supp.2d 326, 332 (D.P.R. 2005) (internal
19 citations, brackets and quotation marks omitted).

20 **FACTUAL BACKGROUND**

21 Angel was diagnosed with Insulin Dependent Diabetes ("IDDM" or
22 "Type I Diabetes") when he was between seven and nine years old. He
23 was treated by Dr. Miriam N. Alicea, a pediatric endocrinologist,
24 until he turned 18 years old.
25
26

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3 IDDM is a syndrome characterized by hyperglycemia (high blood
4 glucose levels) resulting from absolute or relative impairment in
5 insulin secretion and/or insulin action.

6 DKA is a metabolic disorder that occurs when blood glucose levels
7 are high (hyperglycemia) and insulin levels are low.

8 In Type I Diabetes patients, DKA is commonly precipitated by a
9 lapse in insulin treatment or by an acute infection, trauma, or
10 infarction that makes the usual insulin treatment inadequate.

11 Education of diabetes patients is essential, among other
12 reasons, for the effectiveness of prescribed therapy and to recognize
13 indications for seeking medical attention. Blood glucose levels can
14 be tested at home with easy to use home analyzers, using a drop of
15 finger tip blood.

16 Type I Diabetes pediatric patients and their parents are taught
17 to test their blood glucose at least four times a day. Type I
18 Diabetes pediatric patients and their parents are educated about the
19 risk of DKA and how to identify and respond to it when they are first
20 diagnosed with the disease.

21 Type I Diabetes patients are at risk of DKA regardless of the
22 method they use to administer insulin.

23 Dr. Alicea filled out a Prescription and Medical Necessity form
24 used by plaintiffs to purchase a MiniMed 508 Insulin Pump
25 manufactured by defendant.

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2 Insulin pumps or "continuous subcutaneous insulin infusion" are
3 defined as:

4 A mode of intensive insulin treatment in patients with Type
5 I DM [which] involves a small battery-powered infusion pump
6 that provides a continuous subcutaneous infusion of rapid-
7 acting insulin through a small needle, usually inserted in
8 the abdominal wall. The pump is programmed to infuse a
9 selected basal rate of insulin, supplemented by manually
10 triggered or programmed increased rates before each meal.
11 The patient measures glucose levels several times a day to
12 adjust the dosage.

13 Mark H. Beers, M.D. & Robert Berkow, M.D., The Merck Manual of
14 Diagnosis and Therapy (17th ed. 1999) p. 173.

15 Plaintiff purchased a MiniMed 508 Insulin Pump directly from
16 defendant via the internet. The device was shipped to plaintiffs on
17 November 21, 2000 together with a User's Guide in English.

18 On February 16, 2001, Dr. Pijem attended a seminar entitled
19 "Intensive Diabetes Management: Utilizing Insulin Pump Therapy". Dr.
20 Pijem was at that time, and still is, a board-certified Pediatric
21 Endocrinologist and the Director of the Pediatric Endocrinology
22 Department of the University of Puerto Rico School of Medicine.

23 At the aforementioned seminar, Dr. Pijem attended lectures and
24 was provided with written materials. Among those materials was a
25 manual entitled "Pumping Protocol: A Physician's Guide to Insulin

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3
4 Pump Therapy Initiation", authored by Dr. Bruce W. Bode pursuant to
5 an educational grant from MiniMed, Inc. ("the Pumping Protocol").
6

7 The Pumping Protocol was directed both at physicians beginning
8 to prescribe pump therapy as well as those with extensive experience
9 in the matter. MiniMed also provided Dr. Pijem with a MiniMed 508
10 Pump User's Guide.

11 In mid March 2001 Dr. Pijem connected Angel to the MiniMed 508
12 pump.
13

14 On March 31, 2001, Angel was taken to the emergency room at
15 Hospital Interamericano de Medicina Avanzada ("HIMA") in Caguas. At
16 that time the pump was disconnected and it showed that its cannula³
17 was bent which did not allow for the insulin to flow as expected.
18

19 On April 1, 2001, Angel was transferred to the San Jorge
20 Children's Hospital and admitted into its Intensive Care Unit ("ICU")
21 with a diagnosis of DKA and moderate dehydration. On April 2, 2001,
22 Angel's DKA had resolved and he was transferred from the ICU to the
23 ward.
24

25 According to Dr. Julio Albino, plaintiffs' expert witness, Angel
26 could have avoided DKA had he checked his blood glucose levels four
to six times a day.

27 Dr. Albino indicated that had Angel experienced high blood
28 glucose levels while on the pump, he could have taken off the pump;
29

30
31 [A] tube for insertion into a duct or cavity." Dorland's
32 Illustrated Medical Dictionary (W.B. Saunders Co. 25th ed. 1974).
33

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3 taken an injection of regular insulin by syringe to lower his blood
4 glucose levels and contacted a physician for advise.

5 Dr. Albino further noted that Dr. Alicea had the necessary
6 knowledge to lower Angel's blood glucose levels if they were high
7 while Angel was using the MiniMed 508 pump.

8 Plaintiffs did not contact Dr. Alicea to report high glucose
9 levels during March 2001 when Angel was reportedly using the MiniMed
10 508 pump or when his bout of DKA began even though they had her
11 office and home telephone number.

12 Angel was a camper in diabetes summer camps overseen by Dr.
13 Miriam N. Alicea. One of the purposes of these camps was to teach
14 campers the fundamentals of diabetes care as well as learn good
15 health habits such as proper diet, blood glucose monitoring, insulin
16 dose adjustment and exercise. Angel learned about the pump through a
17 camp counselor.

18 Dr. Alicea teaches her patients to test their urine for ketones
19 whenever their blood glucose levels exceed 240 mg/dl.

20 According to Dr. Alicea, given the years as a diabetes patient
21 and attendance at diabetes camp, in March of 2001 Angel knew or
22 should have known that two or more blood glucose level readings above
23 240 milligrams per deciliter indicate a risk of ketoacidosis and that
24 he should check for ketones.

25 Dr. Alicea filled out the prescription form for the pump but was
26 not familiar with the device. Dr. Alicea acknowledged that she never

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3 managed a patient with a pump because she did not have any training
4 in this technology.

5 **THE CLAIMS**

6 Inasmuch as this is an action based on diversity of citizenship
7 Puerto Rico substantive law is used to determine liability. Correa
8 v. Cruisers, 298 F.3d 13, 22 (1st Cir. 2002).

9 Ascertaining which are the specific claims asserted in these
10 proceedings in order to properly address their viability has proved
11 a difficult task. Even though the complaint only makes mention of
12 negligence claims, in their memoranda plaintiffs have also included
13 arguments pointing to defendant's alleged responsibility for breach
14 of its duties under products liability doctrines.

15 Upon reviewing the only complaint on file we must reach the
16 inescapable conclusion that the claims asserted therein are
17 predicated exclusively on the negligent acts or omissions of Dr.
18 Pijem. It is noteworthy that the complaint explicitly labeled the
19 action as a "Medical Malpractice" suit. In this vein, the pleading
20 specifically avers that Dr. Pijem did not ensure that the "device was
21 well connected, adequately managed and was functioning properly",⁴ and
22 also failed to evaluate, treat and/or refer Angel to another
23 physician or for testing in light of his complaints.⁵ Even though
24 plaintiffs were granted leave to amend their complaint to include

25 ⁴ Complaint (docket No. 1) ¶ 19.

26 ⁵ Id. ¶¶ 21-22.

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3 allegations regarding malfunction of the equipment due to an alleged
4 failure in the alarm system the amended pleading was never filed.⁶

5 In sum, in the outstanding pleading MiniMed is charged only with
6 vicarious liability premised on the conduct of Dr. Pijem, its
7 purported local representative. Plaintiffs specifically allege that
8 the damages complained of "are [the] direct cause of the negligence
9 of MiniMed, and their representative Dr. Gonzalez de Pijem."⁷

10 In pertinent part, the pleading describes MiniMed's negligence
11 as follows:

12 ¶32. MiniMed (sic) representative was not capable of
13 effectively and safely performing the important task of
14 installing the insulin pump, which is a life depending
15 device... [despite] her lack of training and education and
16 even without the necessary skills, MiniMed authorized her
17 to do it. In this particular case, her mishandling,
18 wrongful... connection of the device and mistreatment
19 (sic) of the minor resulted in a near death situation and
20 its consequences for which MiniMed and their representative
21 should respond.

22 ¶33. Such disregard by defendants of the health of the
23 minor and by referring the minor to obtain the medical

24 ⁶ See Motion Requesting Permission to Amend Complaint, filed on
25 July 2, 2005 (docket No. 34) and Order granting the request, issued
on July 21, 2005 (docket No. 35).

26 ⁷ Complaint (docket No. 1) ¶ 31.

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3 services of connecting a life depending device without the
4 proper training and knowledge was the proximate cause of
5 the critical medical condition the minor underwent....

6 No failure to warn or other product liability claim aimed
7 directly at defendant's acts or omissions even remotely appears pled
8 in the complaint. Rather, plaintiffs charge Dr. Pijem under the
9 negligence doctrine of informed consent whereby she allegedly failed
10 in her duty to fully disclose relevant information regarding the
11 MiniMed pump as well as the device's known risks and advantages. In
12 pertinent part, the pleading avers that Dr. Pijem "never advised the
13 [plaintiffs] of any consequences, possible malfunctions or situations
14 to be alert, which constituted a violation of the informed consent
15 obligation".⁸

16 Having clarified the precise nature of the claims asserted in
17 these proceedings we now proceed to determine whether or not summary
18 judgment is in order.

19 **Apparent Authority**

20 Defendant argues that it should not be held accountable for Dr.
21 Pijem's purported negligent acts or omissions inasmuch as she was not
22 its employee but rather an independent contractor. Plaintiffs, on the
23 other hand, aver that based on defendant's representations they were
24 led to believe that Dr. Pijem was MiniMed's agent in Puerto Rico.

25
26 ⁸ Complaint (docket No. 1) ¶ 18.

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3 Apparent authority may subject a principal to liability when a
4 third party reasonably believes that an actor has authority to bind
5 that principal based on the principal's representations. In order to
6 prove apparent authority plaintiffs must establish that they relied
7 in good faith in the conduct before them which conduct would lead a
8 reasonable person to believe that a principal-agent relationship
9 indeed existed. Vega v. Admin. Servs. Medicos, 117 D.P.R. 138, 147
10 (1986). This doctrine, which is based on equitable principles,
11 provides that a principal is estopped from disclaiming an agency
12 relationship before a third party where it has expressly or
13 implicitly led the third party to believe that such a relationship
14 exists. Berrios Pagan v. Univ. of P.R., 116 D.P.R. 88, 102 n.2
15 (1986).

16 According to plaintiffs, upon purchasing the pump MiniMed
17 referred them to Dr. Pijem, their "representative".⁹ Angel's mother,
18 Mrs. Rosa, further indicated that Dr. Pijem regretted having to spend
19 time taking the training and connecting the pumps because she was
20 only going to be paid \$200.00 which did not compensate for the time
21 this process entailed given her years of professional preparation.
22 Plaintiffs had never met Dr. Pijem prior thereto.

23 Absent evidence contradicting plaintiffs' assertion regarding
24 the alleged representations made by MiniMed with respect to its

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26 ⁹ Maria de los A. Rosa depo. Tr. 107.

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3 relationship with Dr. Pijem, summary judgment on this issue in
4 defendant's favor is not viable.¹⁰

5 **Causal Relationship**

6 Defendant contends that the exclusive proximate cause of Angel's
7 DKA was plaintiffs' failure to take ordinary care measures expected
8 of a Type I Diabetes pediatric patient to manage his glucose levels
9 and avoid DKA. According to movant, these measures include testing
10 urine for ketones whenever blood glucose levels exceed certain values
11 and seeking medical help prior to developing DKA. Specifically,
12 defendant avers that Angel should have closely monitored his blood
13 glucose levels and taken the necessary steps to remedy the situation
14 such as disconnecting the insulin pump, switching to an injection of
15 regular insulin and seeking immediate medical attention.

16 In support thereof, defendant notes that Angel had been
17 diagnosed with Type I Diabetes for over six years prior to the DKA
18 incident and had been under the care of Dr. Alicea since 1995. Dr.
19 Alicea testified that she had educated Angel and his parents in
20 glucose monitoring both at her office as well as during camps
21 organized by her.

22 Art. 1802 of the Puerto Rico Civil Code, 31 P.R. Laws Ann.
23 § 5141 (1990), governs tort liability in Puerto Rico. According to
24 this provision, a person is liable for damages resulting from his/her

25 ¹⁰ Given the fact that plaintiffs are pursuing liability under
26 the apparent authority doctrine there is no need for us to address
defendant's learned intermediary defense.

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3 negligent acts or omissions. In order to prevail, plaintiff must
4 establish: (1) a negligent act or omission, (2) damages, and (3) a
5 causal relationship between them. Irvine v. Murad Skin Research
6 Laboratories, Inc., 194 F.3d 313, 321-322 (1st Cir. 1999); De-Jesus-
7 Adorno v. Browning Ferris Indus. of P.R., Inc., 160 F.3d 839, 842 (1st
8 Cir. 1998); Marshall v. Perez Arzuaga, 828 F.2d 845, 847 (1st Cir.
9 1987); Pons Anca v. Engebretson, 160 D.P.R. 347 (2003); Montalvo v.
10 Cruz, 144 D.P.R. 748, 758 (1998); Toro-Aponte v. E.L.A., 142 D.P.R.
11 464, 473 (1997).

12 Plaintiff must establish that the conduct at issue was the
13 factor which most probably caused the damages and the cause and
14 effect relationship between both. Soto Cabral v. E.L.A., 138 D.P.R.
15 298, 316 (1995). The mere fact that injuries or damages ensue is not
16 grounds for liability under art. 1802 for that would entail absolute
17 liability. Defendants will be liable only for those reasonably
18 foreseeable consequences to their conduct. De-Jesus-Adorno, 160 F.3d
19 at 842; Pons Anca, 2003 TSPR 150, 2003 WL 22399583, *3-3; Montalvo,
20 144 D.P.R. at 755; Toro-Aponte, 142 D.P.R. at 473; Ocasio Juarbe v.
21 Eastern Airlines, Inc., 125 D.P.R. 410, 418 (1990) Official
22 translation reproduced in full in 902 F.2d 117 (1st Cir. 1990);
23 Jimenez v. Pelegrina Espinet, 112 D.P.R. 700, 704, 1982 WL 210615
24 (1982); Pacheco v. A.F.F., 112 D.P.R. 296, 300 (1982).

25 Further, this is a comparative negligence jurisdiction. Art.
26 1802 specifically provides that the negligence of a plaintiff will

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3 not bar a tort-based claim but rather that the relief awarded shall
4 be reduced proportionate to the degree of plaintiff's negligence.
5 Pons, 160 D.P.R. at 362.

6 While the record reveals that both Angel and his parents were
7 indeed instructed on how to monitor and manage his glucose levels
8 well before the DKA incident as defendant contends, there is also
9 admissible evidence on record pointing to the fact that Angel's prior
10 experience was with long-acting insulin via syringes and not with the
11 short-acting insulin to be dispensed by the pump. Further, according
12 to Dr. Rebecca Saenz, an endocrinologist who treated Angel while
13 hospitalized for DKA at the San Jorge Hospital, when a pump is first
14 connected the patient is initially started with saline for two or
15 three days to ensure that he can handle it as well as to allow an
16 opportunity for the patient to get acquainted with the pump.¹¹ There
17 is no evidence that this procedure was followed in Angel's case.

18 The mother indicated that she was very nervous because of
19 Angel's unusually high glucose levels for which reason she consulted
20 Dr. Pijem daily. Mrs. Rosa stated that she called the physician every
21 day after the connection because her son's glucose levels had risen
22 over 200 which had never happened before. Mrs. Rosa testified that
23 the physician responded that there was no problem, that it was due to
24 the changes due to the new machine and the different type of insulin
25 used.

26 ¹¹ Dr. Saenz depo. Tr. 49.

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3 According to Mrs. Rosa, by the third or fourth day Dr. Pijem
4 responded in an annoyed manner at Mrs. Rosa, insisting as she had
5 previously indicated, that the situation was normal. Angel's mother
6 stated that she called for four or five days after the pump was
7 connected. Thereafter she could not call because Dr. Pijem went on a
8 trip.

9 Mrs. Rosa explained that she did not call Dr. Alicea during this
10 period of time because the physician had previously indicated that
11 even though she would continue to be Angel's physician she had no
12 knowledge regarding the pump and therefore, could not assist in
13 matters related to it. Angel's mother explained that she understood
14 that Dr. Pijem was in charge of all matters related to the pump given
15 the fact that she had installed the equipment. Further, given Dr.
16 Pijem's position as Director of Endocrinology at the University of
17 Puerto Rico School of Medicine they were confident in following her
18 advise.

19 The record does reflect that plaintiffs took prompt and, what
20 seemed to them at the time, a reasonable recourse in responding to
21 Angel's unusually high glucose levels. Mrs. Rosa explained how she
22 alerted Dr. Pijem of the abnormal situation as early as the day
23 following the pump installation and for a number of days thereafter
24 only to be appeased by the physician who suggested that it was part
25 of Angel's adaptation process to the pump. As plaintiffs noted, Dr.
26 Pijem's qualifications were outstanding and there was no apparent

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2 reason for them to doubt her professional judgment particularly, when
3 she was the person who had installed the pump. Further, Dr. Alicea,
4 Angel's endocrinologist, acknowledged that she had alerted plaintiffs
5 to the fact that she could not and would not monitor the pump because
6 she lacked any training regarding the equipment.
7

8 Hence, we find that there are material facts in controversy
9 regarding the proximate cause of Angel's DKA. Contrary to defendant's
10 position that the damages claimed in the complaint ensued exclusively
11 due to Angel's failure to adequately monitor his glucose levels¹² and
12 take the necessary measures in response thereof, there is ample
13 evidence to support plaintiffs' theory that their acts or omissions
14 resulted instead from plaintiffs' reliance on Dr. Pijem's purportedly
15 erroneous advise.

16 Informed Consent

17 As previously noted, in their complaint plaintiffs adduced a
18 claim based on the alleged lack of informed consent.¹³
19

20 ¹² Defendant suggests that because Angel's notations of his
21 glucose levels after March 2001 are not available we should draw an
inference that he never tested for glucose during this period.
22 However, Angel testified that he threw those notations away and we
see no grounds for the negative inference suggested by defendant on
the record currently before us.

23 ¹³ Given the nature of the claims asserted in the pleadings,
24 there is no need for us to entertain defendant's arguments regarding
25 MiniMed's duty to warn customers regarding hazards posed by the use
of its products under strict liability principles inasmuch as no such
cause of action has been alleged. See i.e., Cruz-Vargas v. R.J.
Reynolds Tobacco Co., 348 F.3d 271 (1st Cir. 2003) (products liability
26 claim based on failure to warn doctrine).

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3 "The right of every patient to self-determination, that is, to
4 freely decide what can be done with his or her body, is protected by
5 the courts. As a rule, it implies the prior informed consent by the
6 patient... This does not mean that physicians are obliged to give
7 their patients a complete course in medicine, but it does oblige them
8 to keep them adequately informed about the nature of the treatment,
9 the risks and complications involved, and the benefits expected."

10 Sepulveda v. Barreto, 1994 P.R. Offic. Trans. 908, 876, 137 D.P.R. 735
11 (1994).

12 "[A] patient suing for lack of informed consent does not need to
13 prove a separate negligent act, other than the lack of informed
14 consent." Cruz Aviles v. Bella Vista Hosp., Inc., 112 F.Supp.2d 200,
15 202 (D.P.R. 2000). He must, however, present evidence of damages as
16 well as a causal relationship between the failure to provide adequate
17 information and the damages. *Id.* See also, Santiago v. Hosp. Cayetano
18 Coll y Toste, 260 F.Supp.2d 373, 385 (D.P.R. 2003).

19 Apparently, Angel's connection was either the first or one of
20 the first occasions in which Dr. Pijem installed an insulin pump.
21 According to Angel's mother, the physician did not appear proficient
22 at what she was doing and kept referring back to some written
23 instructions.

24 Mrs. Rosa testified in her deposition that apart from having to
25 change the cannula Dr. Pijem did not give them any explanations

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2 regarding the pump.¹⁴ However, Dr. Gildred Colon, defendant's expert
3 witness, opined in her report that even though a written informed
4 consent document was not warranted prior to initiating pump therapy,
5 she did acknowledge that "[v]erbal and/or written documentation of
6 pros and cons of pump therapy, complications, troubleshooting etc.,
7 like in a manufacturer's manual of safe use" was necessary.

8 The fact that there was printed material accompanying the pump
9 purchased by plaintiffs which explained the risks involved with its
10 use as well as the steps to be taken in case of a problem is not
11 conclusive for purposes of the lack of informed consent claim. It
12 appears that this information was written only in English which
13 plaintiffs did not understand. In her deposition Dr. Pijem conceded
14 as much.

15 Q. Now, during the course of our meetings with Angel Diaz
16 and his family, did Angel tell you that he couldn't
17 read the user's guide because it was in English?

18 A. I had the feeling that they didn't understand English
19 too well, but I can't remember whether he came out and
20 said so or his family said, but I had the feeling he
21 couldn't... his knowledge was not very good.

22 Dr. Pijem depo. Tr. 84.

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26 ¹⁴ Maria de los A. Rosa depo. Tr. 108.

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3 Angel's mother also testified in this regard. "I don't know
4 English and [my husband] understands a little".¹⁵ Angel's father only
5 had limited training in the armed forces and had difficulty
6 communicating in English. In his deposition he indicated that he "had
7 quite a problem with [English]."¹⁶

8 In sum, based on the record before us, whether or not Dr. Pijem
9 had a duty to provide plaintiffs with particular information
10 regarding the benefits of the pump and of any associated risks and
11 complications incidental thereto as well whether or not she did
12 indeed provide such information is a matter to be decided at trial.

13 **Other Claims**

14 In response to defendant's petition for dismissal, plaintiffs
15 further argue that: (1) the pump was defective because its alarm
16 system was not triggered despite its alleged malfunction and (2)
17 MiniMed violated Puerto Rico's Assistive Technology Equipment
18 Guarantee Act, Law No. 402 of September 9, 2000, P.R. Laws Ann. tit.
19 §§ 851-859 (2006).

20 Inasmuch as none of these allegations appear in the complaint we
21 find plaintiffs are precluded from pursuing such causes of action in
22 these proceedings.

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25 ¹⁵ Maria de los A. Rosa depo. Tr. 69.

26 ¹⁶ José E. Rodriguez depo. Tr. 11.

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3 CONCLUSION

4 Based on the foregoing, Medtronic MiniMed's Motion for Summary
5 Judgment (docket No. **50**) is **DENIED**.¹⁷

6 IT IS SO ORDERED.

7 San Juan, Puerto Rico, this 6th day of May, 2008.

8 S/Raymond L. Acosta

9 RAYMOND L. ACOSTA
10 United States District Judge

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25 ¹⁷ See, Response in Opposition (docket No. **56**); Medtronic
26 MiniMed's Reply (docket No. **63**) and Plaintiffs' Sur Reply (docket No.
73).